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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,555	03/14/2001	Akira Takashima	A33865/090495.0233	3921

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,555

Applicant(s)

Takashima et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-132 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-132 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 3, and 22-26, drawn to a composition comprising a chemotactic factor, classified in Class 530, subclass 351.

II. Claims 1-5, 11, and 22-26, drawn to a composition comprising a chemotactic factor and a device, classified in Class 435, subclass 283.1.

III. Claims 6-7 and 22-30, drawn to a composition comprising a chemotactic factor and an APC stimulating factor, classified in Class 530, subclass 351.

IV. Claims 1, 3, and 22-26, drawn to a composition comprising a chemokine and a reactive hapten, classified in Class 530, subclass 351.

V. Claims 9-10, 22-43, and 127-128, drawn to a composition comprising a chemotactic factor, an APC stimulating factor and an antigen presenting cell loaded with an immunoregulatory molecule, classified in Class 435, subclass 325.

VI. Claims 11-12 and 16-21, drawn to a composition comprising a chemotactic factor, an APC stimulating factor and a device, classified in Class 435, subclass 283.1.

VII. Claims 11, 13, and 16-21, drawn to a composition comprising a chemokine, a reactive hapten and a device, classified in Class 435, subclass 283.1.

VIII. Claims 11-12 and 14-21, drawn to a composition comprising a chemotactic factor, an APC stimulating factor and an antigen presenting cell loaded with an immunoregulatory molecule, classified in Class 435, subclass 325.

IX. Claims 44, 46, 65-69, and 121, drawn to a method of providing an artificial chemotactic factor gradient comprising a chemotactic factor, classified in Class 424, subclass 278.1.

X. Claims 44-48, 54, 65-69, and 121, drawn to a method of providing an artificial chemotactic factor gradient comprising a chemotactic factor and a device, classified in Class 424, subclass 278.1.

XI. Claims 44, 46, 65-69, and 121, drawn to a method for entrapping antigen presenting cells comprising a chemotactic factor and an APC stimulating factor, classified in Class 435, subclass 325.

XII. Claims 51, 66, and 71, drawn to a method for entrapping antigen presenting cells comprising a chemokine and a reactive hapten, classified in Class 435, subclass 325.

XIII. Claims 44, 46, 65-69, and 121, drawn to a method of for loading antigen presenting cells comprising a chemotactic factor, an APC stimulating factor, and an immunoregulatory molecule, classified in Class 435, subclass 325.

XIV. Claims 54-55 and 59-64, drawn to a method for entrapping antigen presenting cells comprising a chemotactic factor, an APC stimulating factor, and a device, classified in Class 435, subclass 325.

XV. Claims 54, 56, and 59-64, drawn to a method for entrapping antigen presenting cells comprising a chemokine, a reactive hapten, and a device, classified in Class 435, subclass 325.

XVI. Claims 54-55 and 57-64, drawn to a method of for loading antigen presenting cells comprising a chemotactic factor, an APC stimulating factor, an immunoregulatory molecule, and a device, classified in Class 435, subclass 325.

XVII. Claims 87-109, 124-126, and 131-132, drawn to a vaccine comprising a chemotactic factor, an APC stimulating factor, and an immunoregulatory molecule, classified in Class 424, subclass 278.1.

XVIII. Claims 110-118, drawn to a vaccine comprising a chemotactic factor, an APC stimulating factor, an immunoregulatory molecule, and a device, classified in Class 424, subclass 278.1.

XIX. Claim 119, drawn to a vaccine comprising a chemotactic factor, an APC stimulating factor, an immunoregulatory molecule, and a device, classified in Class 424, subclass 278.1.

XX. Claims 87-109, 124-126, and 131-132, drawn to a method of regulating an immune response comprising a chemotactic factor, an APC stimulating factor, and an immunoregulatory molecule, classified in Class 424, subclass 278.1.

XXI. Claims 110-118, drawn to a method of regulating an immune response comprising a chemotactic factor, an APC stimulating factor, an immunoregulatory molecule, and a device, classified in Class 424, subclass 278.1.

XXII. Claim 119, drawn to a method of regulating an immune response comprising a chemotactic factor, an APC stimulating factor, an immunoregulatory molecule, and a device, classified in Class 424, subclass 278.1.

2. Inventions I-VIII and XIV-XIX are different products. The products comprise different combinations of components with different immunological properties. For example, the addition of immunoregulatory components would significantly alter the composition's immunostimulatory capacity whereas the addition of APC stimulating components might alter the composition's immunolocalizing properties. Therefore the methods are patentably distinct.

3. Inventions I-VIII and XIV-XIX, and IX-XVII and XX-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in materially different processes, such as for *in vitro* assays.

4. Inventions IX-XVII and XX-XXII are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to methods comprising mutually exclusive subgenres of components and further comprising different method steps.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Regardless of whichever Group Applicant elects, Applicant is further required under 35 U.S.C. § 121 to elect:

A) a **specific** chemotactic factor, if any of Groups I or IX is elected.

B) a **specific** chemotactic factor and a **specific** device, if any of Groups II or X is elected.

C) a **specific** chemotactic factor and a **specific** APC stimulating factor, if any of Groups III or XI is elected.

D) a **specific** chemokine and a **specific** reactive hapten, if any of Groups IV or XII, is elected.

E) a **specific** chemotactic factor, a **specific** APC stimulating factor, and a **specific** immunoregulatory molecule, if any of Groups V, XIII, XVII, or XX (if appropriate), is elected.

F) a **specific** chemotactic factor, a **specific** APC stimulating factor, and a specific device, if any of Groups VI or XIV is elected.

G) a **specific** chemokine, a **specific** reactive hapten, and a specific device, if any of Groups VII or XV is elected.

H) a **specific** chemotactic factor, a **specific** APC stimulating factor, a **specific** immunoregulatory molecule, and a specific device, if any of Groups VIII, XVI, XVIII, XIX or XXI-XXII (if appropriate), is elected, and list all claims reading thereon. Currently Claims 1-4, 6-20, 22-25, 27-47, 49-63, 65-68, 70-91, 93-117, and 119-132 are generic.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different chemotactic factors, such as MCP-3 or ADP, have significantly different chemical structures and function through different mechanisms. The different devices, such as osmotic pumps or ceramic composites, have significantly different chemical structures. The different APC stimulating factors, such as reactive haptens or ultraviolet radiation, have significantly different chemical structures and function through different mechanisms. The different immunoregulatory molecules, such as IL-2 or IL-4, have significantly different immunological properties. Therefore, the species are independent and patentable over one another.

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8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 12, 2002

Pat. J. Nolan
Patrick J. Nolan, Ph.D.
Primary Examiner
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